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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE 09/388,090 09/01/99 **JACKSON** W 7969-082 **EXAMINER** HM12/0214 PENNIE & EDMONDS LLP DEVI,S 1155 AVENUE OF THE AMERICAS ART UNIT PAPER NUMBER NEW YORK NY 10036-2711 1641 **DATE MAILED:** 02/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary

Application No. 09/388,090 Applicant(s)

Jackson et al.

Examiner

S. Devi, Ph.D.

Group Art Unit 1641

X Responsive to communication(s) filed on Sep 1, 1999	
☐ This action is FINAL.	
☐ Since this application is in condition for allowance except in accordance with the practice under <i>Ex parte Quayle</i> , 19	
A shortened statutory period for response to this action is set is longer, from the mailing date of this communication. Failur application to become abandoned. (35 U.S.C. § 133). Exten 37 CFR 1.136(a).	e to respond within the period for response will cause the
Disposition of Claims	
	js/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
☐ Claim(s)	
Claim(s)	
Claim(s)	
Application Papers ☐ See the attached Notice of Draftsperson's Patent Draw	ring Review, PTO-948.
☐ The drawing(s) filed on is/are objection	ected to by the Examiner.
☐ The proposed drawing correction, filed on	is approved disapproved.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
☐ Acknowledgement is made of a claim for foreign priori	ty under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies	of the priority documents have been
☐ received.	
received in Application No. (Series Code/Serial N	•
received in this national stage application from the	ne International Bureau (PCT Rule 17.2(a)).
☐ Acknowledgement is made of a claim for domestic price	ority under 35 U.S.C. 9 119(e).
Attachment(s)	
□ Notice of References Cited, PTO-892	N-(-)
☐ Information Disclosure Statement(s), PTO-1449, Paper	NO(S).
☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-	.048
☐ Notice of Informal Patent Application, PTO-152	
I Notice of informati atonic Application, 1 10 102	
SEE OFFICE ACTION OF	N THE FOLLOWING PAGES

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DETAILED ACTION

Election/Restriction

- 1) Claims 1-47 are under prosecution.
- Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 14-36, drawn to an isolated NGSP polypeptide of *Neisseria* spp., an antigenic composition, a vaccine composition and a pharmaceutical composition comprising the polypeptide, classified in class 530, subclasses 350 and 825.
 - II. Claims 10-13, drawn to an antibody that specifically binds to NGSP polypeptide, classified in class 530, subclass 388.4.
 - III. Claims 37-41 and 44, drawn to an isolated DNA comprising a nucleotide sequence encoding the NGSP polypeptide and a plasmid, classified in class 536, subclass 23.1.
 - IV. Claims 42 and 43, drawn to a method of producing an immune response in an animal by immunizing with NGSP polypeptide, classified in class 424, subclasses 190.1 and 249.1.
 - V. Claim 45, drawn to an antagonist, classified in class 530, subclass 300.
 - VI. Claims 46 and 47, drawn to a method for identifying compounds or an agent that interacts with or inhibits NGSP, classified in class 435, subclass 7.2.
- 4) Inventions I, II, III, IV, V and VI are distinct from one another. Inventions I, II, III and V

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are drawn to four distinct products: a polypeptide; an antibody; a DNA and a plasmid, and an antagonist. These products are distinct from one another structurally, physicochemically, functionally, immunologically and/or biologically. Further, the polypeptide of invention I can be produced without using the nucleotide sequence of invention III, for example, by chemical synthesis.

Inventions IV and VI are directed to two independent and distinct methods, which differ from one another in method steps, parameters and reagents or compositions used, and/or ultimate goals accomplished. The method for identifying compounds or an agent is unrelated to the method of producing an immune response in an animal by immunization.

Inventions I and IV are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptide of invention I can be used in a materially different process, for example, as a source of coating antigen in an *in vitro* diagnostic assay to measure polypeptide-specific antibodies.

Inventions I and VI are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptide of invention I can be used in a materially different process, for example, as a source of immunogen in laboratory animals to raise polypeptide-specific antiserum reagents.

Inventions II, III and V are unrelated to inventions IV and VI, because the products of inventions II, III and V are not required to practice the methods of inventions IV and VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

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Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

- Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).
- Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A telephone message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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S. Devi Patent Examiner 03 February 2000



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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PLEASE NOTE:	THIS FACSIMILE NUMBER IS TO BE USED ONLY
FAX/TELECOPIER	NUMBER: (703) 305-3704
SERIAL NUMBER:	
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TO EXAMINER: D	r. S. Devi
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PAGES, INCLUDIN	IG COVERSHEET:
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FROM/ATTORNEY	' :
DATE:	

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